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K013021 1/3

Attachment 11

510(k) Summary

LightLance™ Laser Skin Perforator

Submitted by:

Innotech USA, Inc.
Laser Devices Division
2975 Westchester Avenue, Suite 401
Purchase, NY 10577

September 4, 2001

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Contact Person: Howard M. Holstein, Partner
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Phone: (202) 637-5813
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K013021 2/3

2. **Device Name and Classification:**

Trade Name:	LightLance™ Laser Skin Perforator
Classification Name:	Laser instrument, surgical, powered
Common Name:	Laser Skin Perforator
Classification Panel:	General and Plastic Surgery: Panel 79
CFR Section:	21 CFR §878.4810
Device Class:	Class II

3. **Substantial Equivalence:**

The LightLance™ Laser Skin Perforator substantially equivalent to the current, legally marketed **LASETTE™** (k983673) and (k981746). The **LightLance™ Laser Skin Perforator** has the same intended use and general and specific indications as both of predicated Lasette devices. These devices have very similar principles of operation and technological characteristics. The minor technological differences do not raise any new questions of safety and effectiveness. Performance data demonstrates that LightLance™ is as safe and effective as the Lasette.

4. **Device Description**:

The **LightLance™ Laser Skin Perforator** is a pulsed erbium doped yittrium-aluminum-garnet (Er:YAG) laser. It outputs a single pulse of laser light with a wavelength of 2940 nm, which ablates a small hole in the skin to a depth sufficient to access capillary blood.

K013021 3/3

5. **Intended Use/Indications for Use:**

The **LightLance™ Laser Skin Perforator** is intended to be used for ablation of skin tissue to establish capillary blood access. The LightLance™ Laser Skin Perforator general indication for use is for the perforation of skin to draw capillary blood for screening purposes. The device is specifically indicated for obtaining capillary blood samples for subsequent analysis of blood glucose concentration in both institutional and home settings.

6. **Performance Data:**

The LightLance™ Laser Skin Perforator has been thoroughly tested according to international standards equivalent to the standard IEC 601. Results from the testing indicate that the device is as safe and effective as the predicate device.

7. **Conclusion:**

The **LightLance™ Laser Skin Perforator** is substantially equivalent to the current legally marketed **Cell Robotics Lasette (k983673, k981746).**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2002

Innotech USA, Inc.
c/o Mr. Howard Holstein
Hogan and Hartson L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K013021
Trade/Device Name: LightLance™ Laser Skin Perforator
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 22, 2002
Received: March 5, 2002

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INNOTECH USA, INC.

INDICATION FOR USE STATEMENT

510(k) Number: New Submission K013021

Device Name: LightLance™ Laser Skin Perforator

Indication for Use:

The LightLance™ Laser Skin Perforator is intended to be used for ablation of skin tissue to establish capillary blood access. The LightLance™ Laser Skin Perforator general indication for use is for the perforation of skin to draw capillary blood for screening purposes. The device is specifically indicated for obtaining capillary blood samples for subsequent analysis of blood glucose concentration in both institutional and home settings

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use X OR Over-the-Counter Use ____

510(k) Number K013021

(per 21 CFR 801.109)

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